MAR 19 2008

ARCHITECT *i*Vancomycin

510(k) Summary (Summary of Safety and Effectiveness

This summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K072036

Preparation Date: 19th July 2007

Applicant Name:
Mr. Joan Guixer
Director of Quality Assurance and Regulatory Affairs
Biokit S.A.
Llica d'Amunt
Barcelona, Spain 08186

Device Name:
Reagents
Classification Name: vancomycin test system
Trade Name: ARCHITECT *i*Vancomycin Immunoassay
Common Name: vancomycin test
Governing Regulation: 862.3950
Device Classification: Class II
Classification Panel: Toxicology
Product Code: LEH

Calibrators: Classification Name: Calibrator, drug specific
Trade Name: ARCHITECT *i*Vancomycin Calibrators (A-F)
Common Name: Calibrator
Governing Regulation: 862.3200
Device Classification: Class II
Classification Panel: Toxicology
Product Code: DLJ

Legally marketed device to which equivalency is claimed:

AxSYM Vancomycin II (K955851)

Intended Use of Device:

The ARCHITECT *i*Vancomycin assay is an *in vitro* chemiluminescent microparticle immunoassay (CMIA) for the quantitative measurement of vancomycin in human serum or plasma on the ARCHITECT *i* System with *STAT* protocol capability. The ARCHITECT *i*Vancomycin assay is used in the diagnosis and treatment of vancomycin overdose and in monitoring levels of vancomycin to help ensure appropriate therapy.

Description of Device:

The ARCHITECT *i*Vancomycin assay is a one-step *STAT* immunoassay for the quantitative measurement of vancomycin in human serum or plasma using CMIA technology, with flexible assay protocols, referred to as Chemiflex.

Sample, anti-vancomycin coated paramagnetic microparticles, and vancomycin acridinium-labeled conjugate are combined to create a reaction mixture. The anti-vancomycin coated microparticles bind to vancomycin present in the sample and to the vancomycin acridinium-labeled conjugate. After washing, pre-trigger and trigger solutions are added to the reaction mixture. The resulting chemiluminescent reaction is measured as relative light units (RLUs). An indirect relationship exists between the amount of vancomycin in the sample and the RLUs detected by the ARCHITECT *i* System optics.

Comparison of Technological Characteristics:

The ARCHITECT *i*Vancomycin assay is a chemiluminescent microparticle immunoassay (CMIA) method for the quantitative measurement of vancomycin in human serum and plasma. The AxSYM® Vancomycin II assay utilizes fluorescence polarization immunoassay (FPIA) technology for the measurement of vancomycin in serum or plasma.

Summary of Non-Clinical Performance:

The ARCHITECT *i*Vancomycin assay is substantially equivalent to the AxSYM Vancomycin II assay in terms of precision, linearity and interferences as demonstrated in non-clinical performance data in this 510(k) submission.

Summary of Clinical Performance:

The ARCHITECT *i*Vancomycin demonstrated substantially equivalent performance to the AxSYM Vancomycin II with a correlation coefficient of 0.996.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 19 2008

Biokit, S.A.
Can Male S/N
c/o Mr. Joan Guixer
Director of Quality Assurance & Regulatory Affairs
Llica d'Amunt
Barcelona, Spain 08186

Re: k072036
Trade Name: ARCHITECT iVancomycin Reagents and
ARCHITECT iVancomycin Calibrators (A-F)
Regulation Name: 21 CFR 862.3950
Regulatory Class: Class II
Product Codes: LEH, DLJ
Dated: March 06, 2008
Received: March 17, 2008

Dear Mr. Guixer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known):

Device Name: ARCHITECT *i*Vancomycin Reagents and ARCHITECT *i*Vancomycin Calibrators (A-F).

Indication For Use:

Reagents

The ARCHITECT *i*Vancomycin assay is an *in vitro* chemiluminescent microparticle immunoassay (CMIA) for the quantitative measurement of vancomycin in human serum or plasma on the ARCHITECT *i* System with *STAT* protocol capability. The ARCHITECT *i*Vancomycin assay is used in the diagnosis and treatment of vancomycin overdose and in monitoring levels of vancomycin to help ensure appropriate therapy.

Calibrators

The ARCHITECT *i*Vancomycin Calibrators are for the calibration of the ARCHITECT *i* System with *STAT* protocol capability when used for the quantitative determination of vancomycin in human serum or plasma.

For *in vitro* diagnostic use.

Prescription Use _X____ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K072036